PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0147-013.B.WO-3	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CH2004/000480	International filing date *(day/month/year)* 02.08.2004	Priority date *(day/month/year)* 31.07.2003
International Patent Classification (IPC) or national classification and IPC A61M1/28, F04B43/12		
Applicant DEBIOTECH S.A. ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 1 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☒	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand 09.06.2005	Date of completion of this report 28.10.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Lakkis, A Telephone No. +31 70 340-4136

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International application No.
PCT/CH2004/000480

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1(b))
   ☐ publication of the international application (under Rule 12.4)
   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-16 as originally filed

Claims, Numbers

5-65 as originally filed
1-4 filed with telefax on 11.10.2005

Drawings, Sheets

1/41-41/41 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing *(specify)*:
   ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing *(specify)*:
   ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

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Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
   ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
   ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

   see separate sheet

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 56-65, 53, 55

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 56-65, 53, 55

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
   - ☐ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
   - ☐ complied with.
   - ☒ not complied with for the following reasons:

     see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. 1-52, 54 (when dependent on 1-52) .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-52,54 (if dependent on 1-52)
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-52,54 (if dependent on 1-52)
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-52,54 (if dependent on 1-52)
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item II.

The subject matter of the embodiments of figures 26-37 and related claims is not covered by the claimed priority.

Re Item III.

Claims 56-65 relate to matter (Method for treatment of the human or animal body by therapy) for which the International Authority is not required to carry out search or preliminary examination, see Rules 39.1(iv) and 67.1(iv) PCT. The patient is undergoing therapeutical treatment since he is being administered a liquid. Moreover, the only described application is in the context of peritoneal dialysis which is clearly a therapeutical treatment.

Claim 55 contains no technical features and therefore relate to an extremely large number of possible apparatus. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the apparatus claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search and examination are impossible. Moreover, claim 55 is also unclear since part of the "pressure sensor for a system..." is already claimed in the system (claim 35) which contains a membrane which "contains a portion which is forming part of a pressure sensor".

Re Item IV.

The separate inventions/groups of inventions are:

1-52, 54 (when dependent on 1-52)
A system for performing fluid administration on a patient comprising two distinct hub chambers where the second hub chamber includes one patient port and at least one drain port and further control means are arranged to close said patient port when said drain port is open and vice versa.

53, 54 (if dependent on 53)

A system for performing fluid administration on a patient comprising a flexible membrane forming a valve seat, the membrane including a clipping mechanism

The present application lacks unity within the meaning of Rule 13 of the PCT for the following reasons:

Systems for performing fluid administration on a patient are well known, see e.g. EP1195171.
Over this state of the art, the potential special technical features claimed in the application document are related to:

1st subject: claims 1-52, 54 (when dependent on 1-52)
two distinct hub chambers where the second hub chamber includes one patient port and at least one drain port and further control means are arranged to close said patient port when said drain port is open and vice versa. Problem solved: providing a simple liquid distribution system which includes only two distinct cavities (see description, page 1, lines 26, 27)

2nd subject : 53, 54 (if dependent on 53) flexible membrane forming a valve seat, the membrane including a clipping mechanism
Problem solved: controlling membrane movement

Apart from the state of the art, no same or corresponding technical features can be found between the above groups of claims. There is thus no technical relationship between the special technical features defined for each of these groups of claims and, therefore, none of the alleged inventions defined in these groups of claims are linked by a common general inventive concept.

Re Item V.

1 The following document is referred to in this communication:
D1 : EP 1 195 171 A (TERUMO CORP) 10 April 2002 (2002-04-10)

The document D1 (figures 8A,B, paragraphs 64-67) is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references in parentheses applying to this document):

a system for performing fluid administration on a patient comprising:
-a liquid pump (87),
-a liquid distribution system connected to said pump in such a way that liquid can flow from the liquid distribution system to the pump and vice versa,
-liquid supply means (4) for supplying liquid to a patient via said liquid distribution system and said pump
-a patient conduit adapted for connecting said liquid distribution system to a patient
-wherein said liquid distribution system comprises two distinct hub chambers (first chamber: portion between clamps 111, 113, 118; second chamber: portion between clamps 114, 117, 118 including the heating conduit), the first hub chamber including at least one liquid supply port with dedicated valve means (111), one patient port with dedicated valve means (118) and one pump inlet (113), the second hub chamber including at least one patient port (117) or warmer port (116) with dedicated valve means and one pump outlet (114), said system furthermore comprising control means arranged to close said patient port (118) of the first hub chamber when said liquid supply port (111) is open and vice versa (see column 11, lines 31-38 and 51-57).

The subject-matter of claim 1 differs from this known system in that the hub chambers are separated by a space.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as the simplification of manufacturing of the liquid distribution system. This is achieved by providing two distinct hub chambers which are separated by a space instead of a complicated system of conduits. There is no hint in D1 for the man skilled in the art to adopt such a geometry. Therefore the solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT).

Similar arguments apply mutatis mutandis to claim 54 (if dependent on claims 1-52), which

therefore is also considered novel and inventive. Claims 2-52 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VIII.

Lack of clarity issues (Article 6 PCT):

-Claims 1, 4: inconsistent use of reference numbers:
warmer port (16) or (19); patient port (16) or (18).
Although reference numbers do no add any limitation to the claim, this inconsistent notation creates unclarity.

-Claims 19, "said port and ports" is unclear

-Claims 24 and 47 are unclear because they refer to trademark names.

-Description, page 1, state of the art: some of the patents quoted as "peritoneal dialysis systems" are none, e.g. EP695397, EP852953, EP0694125 etc.

-Figures 7a, 14a appear not to have a related description.

-In the description, page 9, paragraph 3 refers to Fig. 6" which could not be found.

-In the description, page 1, lines 21-24, the designation of claims as independent or dependent is not correct: claims 1, 53, 54, 55, 56, 65 are independent claims, the rest is dependent.

-Figures 2-13, 14a, 15-18, 21, 23, 24, 26-30, 32 do not meet the requirements of Rule 11.13(a) PCT.

Claims

1. A system for performing fluid administration on a patient comprising :
- a liquid pump (1),
- a liquid distribution system (2) connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,
- liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1),
- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),
characterized by the fact that said liquid distribution system (2) comprises two distinct hub chambers (7,8) which are separated by a space, the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26) , the second hub chamber (8) including at least, one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27), said system furthermore comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa.

2. System according to claim 1 wherein said second hub chamber (8) furthermore includes at least one drain port with dedicated valve means (11). said control means being also arranged to close said patient port (18) of the second hub chamber (8) when said drain port (11) is open and vice versa.

3. A system according to claim 1 or 2 wherein said liquid distribution system (2) only includes two hub chambers (7,8).

4. A system according to anyone of the previous claims furthermore comprising a warmer system (28), a cavity (17) including a warmer port (19) and a patient port (16), said patient port (18) of the second hub chamber (8) being connected to said warmer port (19) via said warmer system (28).